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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 33712P1

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on July 17, 2009

Signature /J. David Gonce/

Typed or printed name J. David Gonce

Application Number	Filed
10/815,127	2004-03-31

First Named Inventor: Ashish A. Patel

Art Unit	Examiner
1611	Kyle A. Purdy

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☐ attorney or agent of record. Registration number _____.
- ☑ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 47,601

/J. David Gonce/
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Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 1 forms are submitted.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Ashish A. Patel, et al.
Application No.:	10/815,127
Filing Date:	March 31, 2004
Confirmation No.:	9219
Title:	Bilayer Tablet Comprising an Antihistamine and a Decongestant
Examiner:	Kyle A. Purdy (571) 270-3504
Group Art Unit:	1609

PRE-APPEAL BRIEF REQUEST FOR REVIEW

MAIL STOP AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Final Office Action dated April 17, 2009, the Applicants hereby file a Notice of Appeal and respectfully request favorable consideration of the arguments presented in this Pre-Appeal Brief Request for Review.

I. Procedural Background.

The present claims are directed to bilayer tablets comprising a first discrete portion which provides a sustained-release of a sympathomimetic drug (such as a decongestant) and a second discrete portion of the tablet which provides an immediate-release of a piperidinoalkanol (such as an antihistamine). Thus, the bilayer tablet advantageously provides an antihistamine (such as fexofenadine) in a form having nearly immediate absorption and bioavailability while at the same time providing a decongestant (such as pseudoephedrine HCl) in a form having efficient sustained-

release bioavailability. In addition, the bilayer tablets exhibit good content uniformity under USP requirements, maintain acceptable physical strength over the shelf life of the tablet.

There are six independent claims in the case (1, 18, 27, 30, 31, and 32). Claims 1, 18, 27, and 31 each specify that the first discrete portion of the tablet includes: (1) from about 10 wt. % to about 60 wt. % of a cellulose binder selected from the group consisting of hydroxypropyl methylcellulose, hydroxypropyl cellulose, and mixtures thereof, wherein the hydroxypropyl cellulose has a molecular weight of at least about 80,000; (2) from about 5 wt. % to about 50 wt. % of ethylcellulose; (3) from about 10 wt. % to about 30 wt. % of a wax selected from the group consisting of stearyl alcohol, cetyl alcohol, carnauba wax, white wax, yellow wax, microcrystalline wax, and mixtures thereof. Claims 30 and 32 each more specifically require that the cellulose binder is hydroxypropyl methylcellulose and that the wax is stearyl alcohol.

The Examiner has finally rejected Claim 1, 18, 27, and 31, contending that the above limitations are obvious over MacLaren (US 6,039,974) taken in combination with Uemura (US 4,695,467) and Staniforth (US 5,858,412). The Examiner has also finally rejected Claims 30 and 32 contending that the above limitations are obvious over MacLaren taken in combination with Uemura, Staniforth, and Okada (US 5,164,193).[1] It is respectfully submitted that the Examiner has clearly erred in making the aforementioned final rejections for at least the following reasons.

II. MacLaren Teaches Away From the Amount of Wax Specified in the Applicants' Claims.

MacLaren, the primary reference, is the only reference to disclose even the basis concept of a bilayer tablet. However, the Examiner concedes that MacLaren fails to disclose or suggest the inclusion of (3) from about 10 wt. % to about 30 wt. % of a wax selected from the group consisting of stearyl alcohol, cetyl alcohol, carnauba wax, white wax, yellow wax, microcrystalline wax, and mixtures thereof. The Examiner attempts to remedy this by reference to Uemura. This argument is unavailing, however, since the modification proposed by the Examiner would seemingly render MacLaren's formulation unsuitable for its intended purpose.

[1] The Bertelsen reference (US 6,713,089) is also included in the prior art rejections of Claims 30 and 32; however, it is the Applicants' understanding that Bertelsen is cited only in regard to the composition of the second, immediate-release portion of the tablet.

Again the MacLaren reference and the Applicants' present invention are directed to bilayer tablets. Uemura, and all the remaining supporting references, are not. The ingredients of a bilayer tablet are typically compressed not once, but twice, as discussed on page 3 of the Applicants' specification making the formulation of a bilayer tablet more difficult than a single layer tablet. The background of MacLaren notes many failed attempts to make workable bilayer tablets which combine antihistamines with sympathomimetic drugs such as decongestants. These are said to have failed due to unacceptable chemical degradation of the active ingredients and /or because the final bilayer tablet exhibited unacceptable cracking and physical strength properties.

MacLaren specifically states that he was trying to overcome such difficulties and provide a bilayer tablet form "of high integrity … such that the tablet resists cracking on standing, has acceptable physical strength, and provides acceptable content uniformity which meets USP requirements." (Col. 2, lines 20 – 26). To that end, MacLaren instructs, not once, but 3 times, that the extended release, decongestant part of the bilayer tablet should include from 59 to about 81 weight percent carnauba wax. (Col. 2, lines 62 – 63; Col. 3, lines 28 – 29; Col. 12, lines 1 – 4) His preferred amount is from 66 to about 74 weight percent. (Col. 4, lines 10 –11; Col. 12, lines 1 – 7). *Thus, MacLaren teaches that the sustained release portion of his tablet should include more than twice as much wax as currently specified in Applicants' claims.* This large difference cannot reasonably be said to be in the range of what one would consider to be an "obvious" modification of MacLaren's teaching.

In view of MacLaren's repeated urgings of the need to use a very high wax content in the sustained release portion of his tablet for a workable formulation, the mere fact that one example in Uemura happens to disclose a "single layer" tablet containing a relatively low amount of carnauba wax cannot reasonably be said to suggest use of small amounts of wax in a bilayer tablet.[2] According to MacLaren, cutting the amount of wax in the sustained release portion of the formulation would render it unsuitable for its intended purpose. Given this, one of ordinary skill in the art trying to make a workable bilayer tablet formulation would not cavalierly ignore MacLaren's teachings based upon Uemera disclosure regarding a single layer tablet.

[2] Notably, the relatively low amount of carnauba wax (25%) used in Example 3 of Uemura is supplemented with an additional 25% of a second wax. This is not surprising since Uemura plainly states that his formulation most preferably includes up to 55% wax (Col. 4, lines 17 – 18).

III. The References Provide No Suggestion to Use Two Different Cellulose Derivatives in the First Portion of the Tablet.

The Examiner further concedes that MacLaren fails to disclose or suggest the inclusion: (1) from about 10 wt. % to about 60 wt. % of a cellulose binder selected from the group consisting of hydroxypropyl methylcellulose, hydroxypropyl cellulose, and mixtures thereof, wherein the hydroxypropyl cellulose has a molecular weight of at least about 80,000; (2) from about 5 wt. % to about 50 wt. % of ethylcellulose. The Examiner attempts to correct this by reference to both Uemura and Staniforth.

While Uemura may refer to the use of cellulose derivatives such as hydroxypropyl methylcellulose (individually) and Staniforth may refer to the use of ethylcellulose (again individually) nothing in the cited reference would lead one of skill to use both types of cellulose derivative, which provide similar functions, in the same layer of a bilayer tablet. Rather, one of ordinary skill would have understood Uemura and Staniforth to simply propose an "either, or" scenario of alternative excipients. Since the two cellulose derivatives provides similar function, one of ordinary skill hypothetically "might" have chosen to use one of these binders, but absolutely nothing in the references would have motivated a person of ordinary skill to use both cellulose derivatives in combination in the same layer. In this regard, the Examiner's argument is similar to arguing that the disclosure of a "belt" in one reference and "suspenders" in a second reference would not have lead one of ordinary skill in the art to redundantly use both a belt and suspenders to accomplish the same task.

Finally, since nothing in these references would suggest using both materials at one time in the same layer, it certainly follows then that nothing would suggest using both materials in the same layer in the specific weight percentages specified in the current claims.

IV. The Addition of Okada Does Not Cure the Faults of MacLaren and Uemura.

Since Claims 30 and 32 specify that the wax used in the sustained release portion of the tablet is stearyl alcohol, the Examiner adds Okada to the aforementioned MacLaren, Uemura, and Staniforth reference as allegedly teaching the use of stearyl alcohol.

Okada refers to stearyl alcohol once at Col. 3, lines 15 – 19 among a veritable encyclopaedia of possible excipients, but Okada's only disclosure of an actual formulation including stearyl alcohol is found in Example 2. However, Example 2 in Okada is directed to a single layer formulation for the sustained release of diclofenac sodium, a non-steroidal anti-inflammatory drug (NSAID). The teachings of Okada would therefore have provided little or not guidance to one of ordinary skill attempting to formulate a bilayer tablet including a tablet portion for the sustained release of a sympathomimetic drug.

V. Conclusion.

In view of the foregoing, Applicants respectfully request that all rejections we withdrawn and that Claims 1 – 8, 10, 12 – 16, and 18 – 32 be allowed. In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our Deposit Account No. 12-2355.

Respectfully submitted,

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